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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/824,527	Applicant(s) KIM ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5-9 and 13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2, 4, 11 and 14 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-9 and newly added claims 10-14 are pending in the instant application. Claims 3, 5-9, and 13 are withdrawn from consideration as being drawn to a non elected invention. Claims 1, 2, 4, 11-12, and 14 are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow, where applicable. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claim 4 under 35 USC 112/2nd paragraph is moot in view of the amendment to the claims to delete the recitation of "chosen from".

Specification

4. The amendment filed 9/20/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification has been amended to change

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a Genbank Accession number from AF35257 to AF352578, at page 18. The response asserts the purpose of the amendment is to correct a typographical error, and that a search of the erroneous number did not provide any sequences in Genbank. In the instant case, the correct number is not readily apparent to the skilled artisan because the specification provides no indication as to what the change should be. As set forth in the MPEP 2163 (I) (B): "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)." The response has not provided any reasoning as to why the skilled artisan would recognize the appropriate correction. For example, as search of "*T. paurometabola*" and "GroEL2" in Genbank did not provide any sequences. Accordingly, the amendment appears to have introduced new matter into the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Enablement

5. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The sequences contained within the Genbank Accession numbers is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). It is known that sequences in Genbank can be changed, such that reference to a Genbank Accession number, as set forth in the claims, does not provide for a fixed sequence. However, the subject matter

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contained in the Accession numbers is essential subject matter for the practice of the claimed invention since in order to make the claimed primer the sequences set forth in the accession numbers must be known. Applicants should note, however, that the Genbank Accession number were not incorporated by reference into the disclosure of the specification, and therefore addition of the sequences into the specification or claims would be considered new matter.

Written Description

6. Claims 2, 4, 11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection includes a New Matter Rejection.

Claim 4 is drawn to nucleic acid sequences which comprise SEQ ID NO: 43.

Accordingly, the claim encompasses a genus of nucleic acids which can contain any number of sequences on either side of SEQ ID NO: 43. The specification teaches that SEQ ID NO: 43 a 420 base pair fragment of the groEL2 gene from a strain of Streptomyces, which is less than a full length coding sequence. Although the claim recites "derived from a potato scab microorganism", the term "derived" appears to indicate that the sequences could also be changed in some way so as to be considered "derived" from an original sequence. Therefore, the partial gene sequence of SEQ ID NO: 43 is not representative of the genus of sequences encompassed by the claims which could be "derived" from potato scab microorganisms.

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Claim 14 is drawn to an isolated groEL2 gene fragment that is produced by amplification from a potato scab microorganisms using SEQ ID NO: 1 and 2. The claims therefore encompass a large genus of fragment produced by amplification with SEQ ID NO: 1 and 2 from any potato scab source. Although the specification teaches that 648 bp fragments were amplified by SEQ ID NOS 1 and 2 for *Streptomyces scabiei*, *Streptomyces acidiscabies*, *Streptomyces turgidiscabies*, *Streptomyces bottropensis*, *Streptomyces disastatochromogens*, and *Streptomyces neyagawanensis*, and further teaches the sequence of smaller 420 bp fragments from within these amplicons, the genus of fragments encompasses those derived from any potato scab source, including other species of *Streptomyces*, such as *Streptomyces europoaiscabies*, *Streptomyces stelliscabiei* and *Streptomyces reticuliscabie* (isolated from netted scab lesions), as well as other organisms such as *Spongospora subterranea subterranea* and *Spongospora subterranea nasturtii* (see Merz, et al; European Journal of Plant Pathology, vol. 11, page 371-379, 2005), which have not been taught or described by the specification. The species disclosed are not representative of the large genus encompassed by the claims because the skilled artisan would not be able to envision the structure of these sequence simply based on the disclosure of the primers of SEQ ID NOS 1 and 2, or the sequences of partial amplicons from *Streptomyces*. As noted by the specification, the 420 bp fragments are variable, which allows for distinction between them, however without a written description of the actual sequences encompassed by the claims, one of skill in the art would not be able to predict their structure.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

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whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acids with SEQ ID NOS: 43-61, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

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Claim 2 has been amended to recite that the primer consists of SEQ ID NO: 2 and “optionally additional nucleotide sequences comprising the complement of adjacent nucleotide sequences of *S. lividans*..., *S. albus*..., and *T. paurometabola*...”, however the specification does not provide any teaching regarding any primer, let alone SEQ ID NO: 2, having the indicated optional nucleotides on either side. The response provides example 1, page 18 as support for this amendment, however the specification at page 18, as well as example 1, do not provide support for a primer with the added claim limitations. The specification does not teach primer sequences with additional sequences on either side of SEQ ID NO: 1 or 2 nor does it provide support for any particular sequences on either side of SEQ ID NO: 1 or 2. Further, claim 2 additionally recites a Genbank Accession number: AF352578 which is not supported by the originally filed specification for the reasons already made of record in the Objection set forth above.

Newly added claim 11 recites “wherein the fragment is 420 or 423 nucleotides long” with regard to the fragment comprising SEQ ID NO: 43 in claim 4. However, while “420” nucleotides is supported by the specification as SEQ ID NO: 43 is 420 nucleotides long, the recitation of “423” is not supported by the specification regarding a fragment which comprises SEQ ID NO: 43. The response asserts that page 11, lines 2-5 provide support for this amendment. However, a thorough review of the specification revealed that although the specification teaches that most fragments from streptomyces species were 420 nucleotides long except for a few species where the fragment is 423 nucleotides long wherein only amino acid is added. However, the specification provides no support for SEQ ID NO: 43 with an additional codon. At page 22, the specification recites “all 420 bp fragments amplified from 40 reference

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strains and 35 potato scab causing strains were determined” but does not provide support for the concept of a fragment comprising SEQ ID NO: 43 specifically, which is 423 nucleotides long.

Accordingly, the amendments have entered new matter into the claimed invention.

Response to Arguments

7. With regard to claim 4, the response traverses the rejection and asserts that “the additional sequence of claim 4 are those that may be found in the sequence of a potato scab microorganism and asserts that most groEL2 genes have a 420 nucleotide sequence but that certain species have an extra codon resulting in a 423 nucleotide sequence. This argument has been thoroughly reviewed but was not found persuasive as the specification does not teach that SEQ ID NO: 43, from *S. scabie* has the extra codon or even whether it would be expected to have the extra codon. Further, as set forth above, the term “derived” appears to indicate that the sequences could also be changed in some way so as to be considered “derived” from an original sequence. As a number of potato scab microorganisms exist other than those whose groEL2 fragments have been taught in the specification, the skilled artisan would not be able to envision the additional sequences which are encompassed by a sequence “derived” from any potato scab microorganism.

Conclusion

8. Claim 1 is allowed.

9. Claim 12 is objected to for being dependent on a rejected claim.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Jehanne Sitton

Jehanne Sitton
Primary Examiner
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12/7/06